Language, Literacy, and Communication Regarding Medication in an Anticoagulation Clinic: Are Pictures Better Than Words?

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Abstract

Objective: Despite the importance of clinician-patient communication for safe medication management, little is known about rates and predictors of medication miscommunication. Measuring rates of miscommunication, as well as differences between verbal and visual modes of assessment, can inform efforts to more effectively communicate about medications. **Methods:** The researchers performed a study among long-term warfarin users in an anticoagulation clinic to assess concordance between patient and clinician reports of patient warfarin regimens. Bilingual research assistants asked patients to (1) verbalize their prescribed weekly warfarin regimen, and (2) identify this regimen from a digitized color menu of warfarin pills. The researchers obtained clinician reports of patient regimens from chart review. Patients were categorized as having regimen concordance if there were no patient-clinician discrepancies in total weekly dosage. Quantitative differences in concordance to the regimen were assessed verbally or visually. The researchers then examined whether verbal and visual concordance rates varied with the patient's language and level of health literacy. **Results:** Fifty percent of patients achieved verbal concordance and 66 percent achieved visual concordance with clinicians regarding the weekly warfarin regimen ($P < 0.001$). In adjusted models, being a Cantonese speaker and having inadequate health literacy were associated with a lower odds ratio for verbal concordance compared to being an English speaker and having adequate health literacy (adjusted odds ratio [AOR] = 0.44, 95% confidence interval [CI] = 0.21–0.93, $P = 0.03$ and AOR = 0.50, 95% CI = 0.26–0.99, $P = 0.04$, respectively). Neither language nor health literacy was associated with visual discordance. **Conclusion:** Clinician-patient discordance regarding patients' warfarin regimen was common, but occurred less frequently when patients identified their regimen with a visual aid. Visual aids may improve the accuracy of medication assessment and may be especially beneficial for patients with communication barriers.

Introduction

Clinician-patient communication regarding medications is a fundamental aspect of health care. Clinicians often need to adjust regimens based on their assessment of what the patient has been taking and the health status of the patient.

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Drugs, such as oral anticoagulants, that have a narrow therapeutic window and require long-term management with frequent dose adjustments require intensive communication. Studies in ambulatory settings have demonstrated that medication-related errors are common.[1] Among older patients, oral anticoagulants are associated with 10 percent of preventable adverse drug events.[2] Effective communication regarding medications can help avoid medication-related errors[3, 4] and has been shown to promote medication adherence in chronic diseases.[5]

Little is known about the quality of clinician-patient communication regarding medications or predictors of medication miscommunication. Studies in internal medicine and cardiology private practices have found discrepancies between self-reported and chart-recorded medication dosages in more than half of patients on at least one medication.[4, 6] Among HIV-infected patients, approximately 25 percent have a discordance between reports of their antiretroviral regimen and what is recorded in the medical chart.[7, 8] In these studies, age,[6] regimen complexity,[4, 7] and limited health literacy[8] were associated with greater discordance. While not all discordance is directly attributable to poor clinician-patient communication, inadequate communication has been shown to predict discordance.[4]

We are unaware of any study that evaluated rates of medication discordance in anticoagulant care. Because discordance between patient and clinician could put patients at risk for poor outcomes, we carried out a study to determine rates of clinician-patient concordance with a prescribed warfarin regimen. Given the prevalence and implications of limited English proficiency[9–11] and limited health literacy, particularly among the elderly[12] and patients with chronic conditions,[13] we also set out to measure whether concordance rates vary by patients' English language fluency and health literacy. Since there is evidence in other settings that clinician-patient communication improves with visual aids,[14, 15] we also explored whether concordance rates vary when patients report their regimen verbally or identify their regimen by use of a visual aid. This research could influence adherence assessment and medication counseling in routine clinical practice[16, 17] and inform interventions to reduce medication-related errors.[1]

Methods

Setting and study participants

We enrolled patients in a cardiologist-supervised, pharmacist-staffed anticoagulation clinic at San Francisco General Hospital (SFGH), the University of California–San Francisco (UCSF)-affiliated public hospital of the City and County of San Francisco. This clinic serves patients who are ethnically diverse and of low socioeconomic status. For non-English speakers, professional interpreter services are generally available.[10] The majority of decisions regarding anticoagulant care are made by anticoagulation clinic pharmacists via a standard algorithm. Patients do not perform home International Normalized Ratio (INR) self-testing. Samples for INR tests are drawn by hospital phlebotomists prior to anticoagulation clinic visits; all values are entered into the hospital's electronic

database. After each visit, clinic pharmacists document the patient's updated regimen and indication for warfarin in the database, which also generates a paper template for the medical record.

Between March 2002 and June 2003, bilingual research assistants attempted to enroll all eligible patients who attended an anticoagulation clinic appointment. Consent to participate was obtained from patients prior to enrollment. Patients were offered $5.00 for their participation. Patients were eligible if they were more than 17 years old and spoke English, Spanish, or Chinese (Cantonese) fluently. We first determined patients' languages and diagnoses by querying the hospital's database. To isolate the impact of communication barriers on regimen concordance from factors due to inexperience with warfarin or differences in practice style or setting, we only included patients who reported being on warfarin and under the care of the SFGH anticoagulation clinic for at least 3 months. We excluded patients with any ICD-9 diagnosis of psychotic disorder, dementia, blindness, or aphasia; those who were too ill to participate; or those who had corrected vision of 20/100 or worse, as these conditions could interfere with health literacy and concordance measurements. We also excluded patients who were using warfarin preparations not on the SFGH or Medicaid formulary (as we would be unable to accurately measure visual concordance with warfarin preparations for which we had no digitized visual menu), patients who reported being colorblind, and patients who had "medi-sets" or pillboxes filled by health professionals. The protocol was approved by the UCSF Human Subjects Committee and SFGH Research Committee.

Measures

Trained bilingual research assistants interviewed patients in the anticoagulation clinic prior to their appointment.

Predictor variables

Research assistants obtained subjects' demographic characteristics, including each subject's primary language and English fluency. Patients who reported speaking English fluently were categorized as English speakers, regardless of their primary language. For English and Spanish speakers, we measured health literacy using the abbreviated version of the short-form Test of Functional Health Literacy in Adults (s-TOFHLA, English and Spanish versions), a reliable, validated measure of health-related literacy.[13, 18–20] Using established convention, we categorized patients as having *inadequate* FHL if the s-TOFHLA score was 0 to 16, *marginal* FHL if it was 17 to 22, and *adequate* FHL if it was 23 to 36.[21]
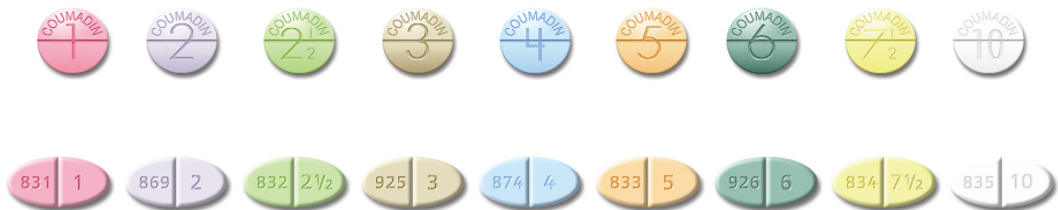
Because health literacy and patient recall may be influenced by unmeasured or undiagnosed cognitive deficits,[22, 23] we measured cognitive ability using the Cognitive Abilities Screening Instrument, shortened version (s-CASI).[24] The s-CASI has been validated in international dementia studies, does not require literacy,[25] and has been shown to accurately measure cognition cross-culturally, including among Asian-language speakers.[26] We used an established cutoff of ≤19 points to categorize patients as having cognitive impairment.

We obtained patients' indications for chronic anticoagulation from an anticoagulation clinic chart review.

Primary outcome measures: regimen concordance

Research assistants asked patients to (1) verbalize their weekly warfarin regimen, and (2) identify this regimen from a digitized color menu of warfarin pills (Figure 1). Specifically, patients were asked: "Can you tell me exactly how you take your warfarin/Coumadin®?" and "Can you show me exactly what you take by pointing to the warfarin/Coumadin® pill or pills?" All patients were prompted to indicate which days of the week they take the medicine, the number of pills they take on these days, and (for the verbal assessment only) the exact number of milligrams per pill on each day. To ensure that our assessment reflected the patient's report as accurately as possible, each of the 7-day reports was reviewed with the patient for his or her final agreement[27] and the total weekly dosage, in milligrams, was calculated separately for the verbal and visual reports. We obtained clinicians' regimen reports from chart reviews, and classified each regimen as "complex" if the prescribed regimen deviated from taking the same pill every day.

Figure 1. Digitized color menu of Coumadin® pills (upper row) and warfarin pills (lower row)

We categorized patients as having *verbal concordance* if there was no patient-clinician discrepancy in the total weekly dosage of warfarin when the patient verbalized the regimen, and *visual concordance* if there was no patient-clinician discrepancy in the total weekly dosage when the patient identified the regimen from the digitized pill menu. Our method of collecting reports of medication regimen and determining concordance was similar to the few published studies of drug regimen knowledge and discrepancy.[6–8, 28] Because the primary goal of our work was to inform communication related to medication assessment, we chose to disentangle verbal from visual reports in assessing concordance, rather than use a composite medication knowledge score employed for research purposes.[8]

Secondary outcome measure: self-reported adherence

Research assistants asked subjects to report their 7-day warfarin adherence using a validated instrument[29, 30] that asks patients to recall the number of days in the past week they missed taking their medication. To encourage honest reporting, each participant was first read a short script that described missing medication as

common for patients with chronic illness. We categorized patients as having perfect adherence if they reported missing no days of warfarin over the prior 7 days, based on their understanding of their regimen.

Statistical analyses

We separately calculated rates of patient-provider warfarin regimen concordance when the patient reported their regimen verbally and visually, and compared proportions using the chi-square test. We then stratified the results by the communication barrier of interest (English, Cantonese, or Spanish language among total sample; inadequate, marginal, and adequate health literacy among English and Spanish speakers). To examine variation in regimen concordance by language, we performed chi-square tests and generated unadjusted odds ratios comparing the odds of achieving (a) verbal concordance, and (b) visual concordance among Cantonese, Spanish, and English speakers. We performed chi-square tests and generated unadjusted odds ratios comparing the odds of (a) verbal concordance, and (b) visual concordance among those with inadequate health literacy versus those with adequate heath literacy.

To isolate the independent effect of language and health literacy on concordance, we used logistic regression analysis. Specifically, we assessed bivariate relationships between the patient's age ($\leq$ or $>$ median age), race/ethnicity, sex, cognitive score (s-CASI $\leq$ or >19), regimen complexity (complex versus straightforward), and—for health literacy analysis only—language (English versus Spanish). We included significant covariates at $P < 0.20$ in multivariate models. For those variables that did not meet our criteria, but for which there is support for inclusion in the literature, we forced them into adjusted models one-by-one to examine what effect, if any, they had on the main effect.

We measured the difference in concordance rates when the report was obtained through the verbal and visual modes, and examined whether the size of the difference between verbal and visual concordance varied by language and health literacy.

To examine the relationship between verbal and visual regimen concordance and self-reported 7-day adherence, we performed separate multivariate analyses as described above.

We estimated that there would be a 10 percent difference in concordance when the regimen was reported verbally versus visually. Under this assumption, we calculated that a sample of 194 patients would have 80 percent power to detect this difference at $P < 0.05$.

Results

We approached 273 consecutive patients identified by the electronic database as meeting eligibility criteria. Of these, 30 were excluded because they reported being on nonformulary warfarin (n = 3), had their medications filled by a medi-set

service or other health professional (n = 10), had visual acuity of 20/100 or worse (n = 5), or were too ill to participate (n = 12). Twenty-six patients refused to participate in the study and 23 patients consented but did not complete the interview. The remaining 220 patients comprised our final sample. Patients who refused to participate or did not complete the interview were not statistically different from the study subjects in terms of their age, sex, language, or race/ethnicity.

Fifty-seven percent of the patients spoke English, 24 percent Spanish, and 19 percent Cantonese. Among English and Spanish speakers (n = 178), 86 (48 percent) had inadequate health literacy, 23 (13 percent) had marginal health literacy, and 69 (39 percent) had adequate health literacy. Most patients were taking warfarin for atrial fibrillation (62 percent) and/or valvular heart disease (26 percent). Fifty-six percent of INRs over the prior 90 days were in the therapeutic range (Table 1).

Table 1. Characteristics of patients (n = 220)

	No.	(%)
Age (median = 59)		
≤ 59	113	(51)
> 60	107	(49)
Sex		
Female	110	(50)
Male	110	(50)
Language		
English	126	(57)
Cantonese	42	(19)
Spanish	52	(24)
Race/Ethnicity		
Asian	87	(39)
Black	31	(14)
Latino	61	(28)
White	41	(19)
Health Literacy* (n = 178)		
Inadequate	86	(39)
Marginal	23	(11)
Adequate	69	(31)
Complex Regimen		
Yes	84	(38)
No	136	(62)
Cognitive Score		
>19	168	(76)
≤19	52	(24)
Indication for Warfarin**		
Atrial Fibrillation	137	(62)
Prosthetic Valve	57	(26)
Prior Stroke/TIA	31	(14)
DVT/PE	29	(13)
Other	10	(5)

Percent of International Normalized Ratios (INRs) in therapuetic range over prior 90 days = 56%.
TIA = transient ischemic attack; DVT = deep-vein thrombosis; PE = pulmonary embolism.
* Sample is limited as health literacy cannot currently be measured among Cantonese-speaking individuals.
** Totals sum to >100% as patients may have more than one indication.

Figure 2 shows verbal concordance rates, both overall and stratified by language and health literacy. Overall, 50 percent of patients' verbal reports of their weekly warfarin regimen were concordant with clinicians' reports. Verbal concordance was lower for Cantonese than English speakers (38 percent versus 56 percent, OR = 0.48, 95% CI = 0.23–0.97, *P* = 0.04). The difference in verbal concordance between Spanish and English speakers did not reach statistical significance (44 percent versus 56 percent, OR = 0.61, 95% CI = 0.32–1.18, *P* = 0.14). Verbal concordance was lower for patients with inadequate versus adequate health literacy (42 percent versus 64 percent, OR = 0.41, 95% CI = 0.21–0.78, *P* < 0.01), but was similar when patients with marginal health literacy and adequate health literacy (61 percent versus 64 percent, OR = 0.88, 95% CI = 0.33–2.33, *P* = 0.80) were compared. In multivariate models, the only covariate significant at *P* < 0.20 was patient age. After adjusting for age, both Cantonese language and inadequate health literacy were independently associated with lower rates of verbal concordance (AOR = 0.44, 95% CI = 0.21–0.93, *P* = 0.03 and AOR = 0.50, 95% CI = 0.26–0.99, *P* = 0.04, respectively). Forcing other covariates into each model, such as the complexity of the regimen or the cognitive score, did not alter the main effect.

Figure 2. Patient-physician concordance rates via verbal assessment of medication regimen, stratified by language and health literacy

P < 0.05 comparing Cantonese to English speakers in adjusted models
**P* < 0.05 comparing patients with inadequate to adequate health literacy in adjusted models
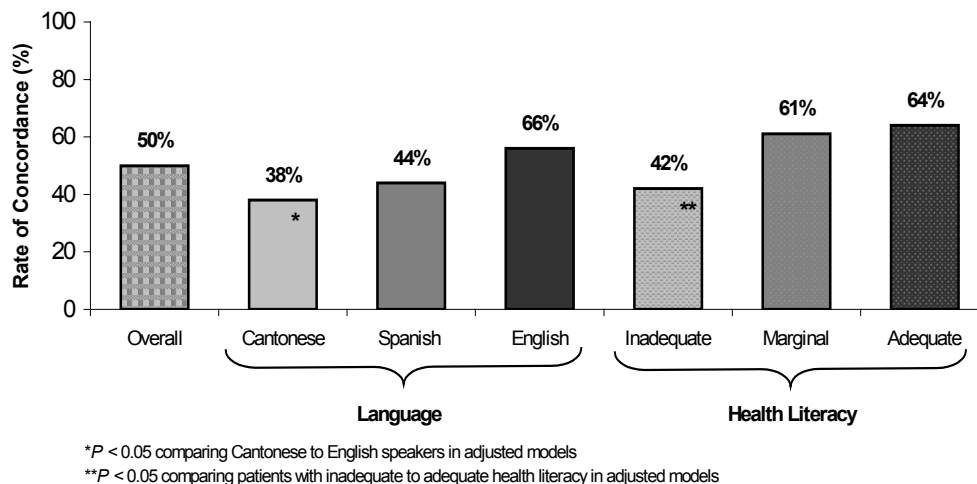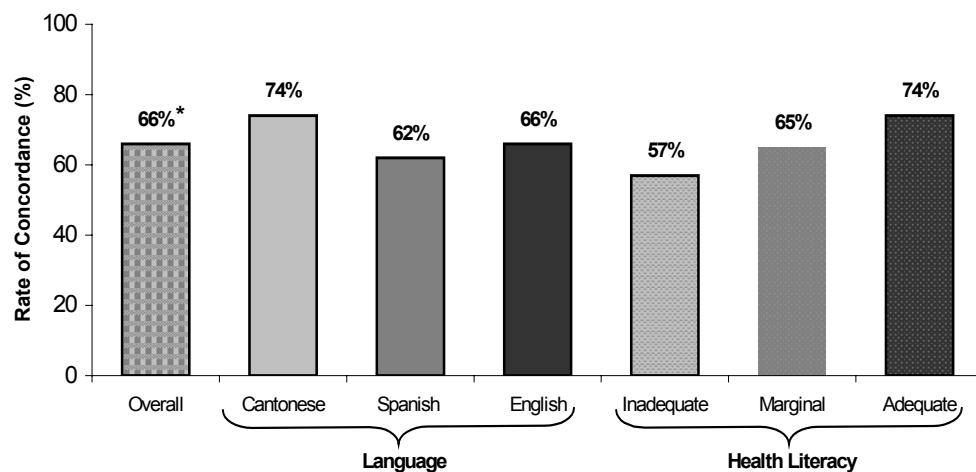
Figure 3 shows visual concordance rates, both overall and stratified by language and health literacy. Two-thirds (66 percent) of patients' visual reports of their regimen were concordant with clinicians' reports (*P* < 0.001 for difference in concordance between verbal and visual modes). Unlike verbal concordance, visual concordance was not different for Cantonese and English speakers (74 percent versus 66 percent, OR = 1.46, 95% CI = 0.67–3.19, *P* = 0.34) or Spanish and English speakers (62 percent versus 66 percent, OR = 0.83, 95% CI = 0.42–1.62, *P* = 0.58). Among English and Spanish speakers, the visual

concordance was lower for patients with inadequate versus adequate health literacy (57 percent versus 74 percent, OR = 0.47, 95% CI = 0.24–0.93, *P* = 0.03), but was not different between patients with marginal health literacy and adequate health literacy (65 percent versus 74 percent, OR = 0.66, 95% CI = 0.24–1.82, *P* = 0.42). In multivariate models, the only covariates that remained significant at *P* < 0.20 were patient age and cognitive score. After adjustment, neither Cantonese language nor inadequate health literacy was associated with lower rates of visual concordance (AOR = 1.46, 95% CI = 0.66–3.23, and AOR = 0.56, 95% CI = 0.27–1.14, *P* = 0.11 respectively).

Figure 3. Patient-physician concordance rates via visual assessment of medication regimen, stratified by language and health literacy
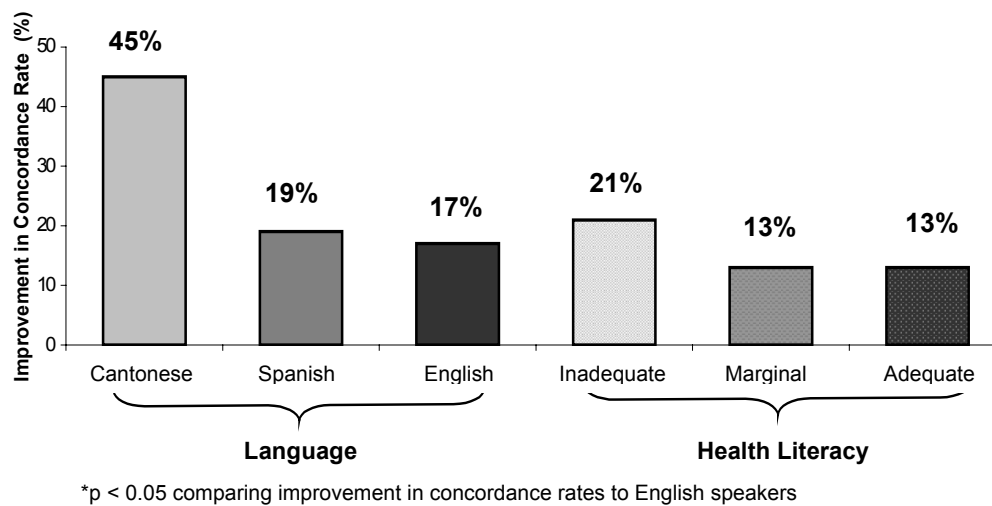

*P < 0.05 comparing visual concordance rates to verbal concordance rates

When patient reports of their regimen were shifted from verbal to visual modes, this was associated with greater patient-provider concordance across all patient subgroups. The improvement appeared to be greatest for those patients with communication barriers; for example, among patients who were verbally discordant (n = 110, Figure 4), Cantonese speakers were more likely than English speakers to become concordant when they reported their regimen with a visual aid (45 percent versus 16 percent raw improvement, OR = 4.38, 95% CI = 2.02–9.48, *P* < 0.001). Similarly, patients with inadequate health literacy were more likely than patients with adequate health literacy to be concordant when they used a visual aid, although this difference was not statistically significant (21 percent versus 13 percent raw improvement, OR = 1.77, 95% CI = 0.74–4.22, *P* = 0.20).

Overall, 183 patients (83.2 percent) reported perfect, 7-day adherence to their warfarin regimen. In multivariate analyses that adjusted for language, cognitive score, and regimen complexity, neither verbal nor visual concordance was associated with patient reports of 7-day adherence (AOR = 1.39, *P* = 0.42 and AOR = 0.43, *P* = 0.09, respectively).

Figure 4. Change in concordance rates when regimen assessed visually, among patients with verbal discordance (n = 110)

*p < 0.05 comparing improvement in concordance rates to English speakers

Discussion

While several studies have identified medication-related discordance as a problem,[4, 6, 7, 28, 31] ours is the first to assess rates of clinician-patient concordance in warfarin regimen, to examine the extent to which communication barriers influence regimen concordance, and to explore the difference in concordance when patients report their regimen verbally or with a visual aid. We found that clinician-patient discordance in the weekly warfarin regimen is common, but occurs less frequently when patients report their regimen using a visual aid. We found that Cantonese language and inadequate health literacy are independently associated with verbal, but not visual, discordance. Shifting assessment from the verbal to the visual mode was more likely to be associated with concordance for patients from all groups, but was particularly helpful for patients with communication barriers. These findings are consistent with other work that reveals that many patients have difficulty deciphering instructions on a medication bottle[17] and/or processing technical information, such as medication instructions conveyed verbally.[27]

Our study has implications for reducing medication-related errors.[32] In the context of chronic disease, effective medication-related communication requires—at a minimum—an accurate assessment of what the patient is taking, as well as an explanation to the patient regarding modifications in the regimen. In anticoagulant care, the components most critical to decisionmaking are (1) the results of the patient's blood work, and (2) the assessment of what the patient has been taking. Clinicians frequently make management decisions by first assessing adherence to the prescribed warfarin regimen through patients' verbal reports.

Inaccuracy in patients' reports, or failure on the part of the clinician to verify these reports, could place patients at risk for poor outcomes.

Our study lends support to the notion that patients most likely to experience errors in medication-related communication are patients with limited English proficiency[11] and/or limited health literacy.[33] Reducing medication-related communication errors among patients with communication barriers likely requires a rigorous review of medication regimens during the assessment phase of a visit. Specifically, using a visual aid may improve the accuracy of patient reports and, by extension, lead to greater regimen concordance between clinician and patient over time. Since medication-related adverse events are common[1] and warfarin is involved in preventable adverse drug events at rates disproportionate to its use,[2] routinely identifying discordance and developing interventions to reduce its occurrence may reduce medication-related errors in anticoagulant care and other settings.[34] Results of studies in other contexts[14, 15, 35, 36] suggest that visual aids can augment verbal communication, particularly for patients with communication barriers. Our own work in the anticoagulation setting suggests that visual aids may ameliorate the negative consequences of regimen discordance on anticoagulant outcomes.[37]

Our findings also have implications for medication adherence assessment in the clinical and research contexts. While there is no gold standard to measure adherence,[16, 38] most experts agree that self-report is the most efficient means to collect adherence data, both for routine clinical work[38] and research.[7, 29, 39] Despite patients' tendencies to overreport adherence because of social desirability,[40] self-report has been linked to clinical outcomes.[39] Our work, however, suggests that the accuracy of patients' reports of adherence may be compromised by unrecognized discordance, insofar as patients may report perfect adherence to an erroneous medication regimen. This provides empiric support to the view developed among some researchers that adherence assessment requires measuring both regimen concordance (regimen knowledge) and medication-taking behavior.[7, 16, 28]

Our study has a number of limitations. First, subjects were recruited from one anticoagulation clinic, which may limit generalizability. Selecting one clinic that uses standard algorithms for medication management and whose sole purpose is to manage one medication permitted us to eliminate much of the influence that system- and provider-related factors may have on variation in regimen concordance. The relatively even distribution of languages and health literacy levels allowed us to explore the impact of communication barriers on medication regimen concordance. While the clinic serves a diverse, low-income population, its performance with regard to anticoagulant outcomes is similar to that of other anticoagulation clinics described in the literature,[41, 42] the self-reported medication adherence rates are similar to those in other chronic disease studies,[5, 34, 39] and concordance rates are similar to those reported in the few studies of regimen discordance that group verbal and visual methods into a composite knowledge score.[6–8]

Second, our method of determining regimen concordance, while similar to those in the few published studies,[6–8, 28] does not allow us to determine (a) whether visual concordance rates were higher than verbal concordance rates because of the order in which we inquired about the regimen; (b) whether discordance occurred because of miscommunication, poor recall, undocumented changes in regimen, or because the clinician was misinformed as to what the prescribed regimen truly should be; or (c) what dosages the patient was actually taking at home. Our inability to include pharmacy dispensing data is unlikely to significantly impact our results, as prior work has revealed that combining such data sources does not change results of models predicting appropriate medication use.[43]

Third, the fact that bilingual research assistants obtained the patient reports raises the possibility that we overestimated concordance rates for patients with limited English proficiency, insofar as the providers' limited non-English language proficiency may lead to lower "real-life" concordance. Similarly, because we designed our study with statistical power to detect differences between verbal and visual concordance, our sample size was likely too small to enable us to detect modest differences in concordance between subgroups of patients; this may explain our findings with regard to Spanish language and concordance. Furthermore, because the study was observational, we cannot rule out the possibility that the associations between limited English proficiency, limited health literacy, and regimen concordance were a consequence of unmeasured confounding. While we attempted to include relevant covariates in models, our questionnaire did not include such factors as the number of medications that patients were taking or the extent to which language interpretation was available during clinical encounters. Finally, while the current study does not address the clinical implications of discordance, we have recently demonstrated that regimen discordance is associated with poor anticoagulant outcomes.[37, 44]

There is growing recognition that communication barriers, such as limited English proficiency and limited health literacy, are associated with lower quality of care and place patients at risk for poor clinical outcomes.[13, 45, 46] Given the prevalence of chronic diseases,[47] the challenge of managing multiple medications, and the incidence of adverse drug events (particularly among the elderly[2]), there is a need to communicate more safely and effectively with patients about medications. We found that, in a sample of diverse, older patients undergoing chronic anticoagulation therapy, clinician-patient discordance in warfarin regimen was common, but occurred less frequently when patients identified their regimen using a visual aid. Assessing adherence without assessing regimen concordance may lead to systematic inaccuracies in adherence assessment and could place patients at risk for preventable adverse drug events. Medication assessment and education may be improved through the use of visual aids, and this mode of communication may be especially beneficial for patients with communication barriers.

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